

REPORT DOCUMENTATION PAGE			Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.				
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE 29.Sep.03	3. REPORT TYPE AND DATES COVERED MAJOR REPORT		
4. TITLE AND SUBTITLE "ETHICAL ISSUES IN HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS IN LATIN AMERICA AND THE CARIBBEAN:DESCRIPTION OF THE PAN AMERICAN HEALTH ORGANIZATION ETHICAL REVIEW		5. FUNDING NUMBERS		
6. AUTHOR(S) MAJ FONSECA-RIVERA JOSE M				
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) UNIFORMED SERVICES UNIV OF HEALTH SCIENC		8. PERFORMING ORGANIZATION REPORT NUMBER CI02-1287		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) THE DEPARTMENT OF THE AIR FORCE AFIT/CIA, BLDG 125 2950 P STREET WPAFB OH 45433		10. SPONSORING/MONITORING AGENCY REPORT NUMBER		
11. SUPPLEMENTARY NOTES				
12a. DISTRIBUTION AVAILABILITY STATEMENT Unlimited distribution In Accordance With AFI 35-205/AFIT Sup		12b. DISTRIBUTION CODE		
13. ABSTRACT (Maximum 200 words)		DISTRIBUTION STATEMENT A Approved for Public Release Distribution Unlimited		
14. SUBJECT TERMS		15. NUMBER OF PAGES 1		
		16. PRICE CODE		
17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT	

20031015 018

ETHICAL ISSUES IN HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS IN LATIN AMERICA AND THE CARIBBEAN: DESCRIPTION OF THE PAN AMERICAN HEALTH ORGANIZATION ETHICAL REVIEW COMMITTEE DECISIONS AND PRACTICES.

Fonseca JM. **Background:** There is growing discussion about the protection of human subjects in biomedical research in Latin America and the Caribbean. However, only a handful of studies have been published about the knowledge, application, and acceptance within the region of international ethical guidelines and standards for human subject research. **Objectives:** To: 1) describe the characteristics of proposals of health research involving human participants in Latin America and the Caribbean (LAC) submitted for review to the ethical committee of the Pan American Health Organization (PAHO ERC); 2) describe the type and frequency of ethical issues identified by PAHO ERC; and 3) review the committee's approval decisions. **Methods:** Retrospective descriptive review of 47 proposal applications submitted to PAHO ERC from September 2001 to March 2003. **Results:** PAHO ERC reviewed projects from 16 (48%) of member states in LAC. Twenty-nine (62%) of projects originated in Brazil, Argentina, Mexico, and Colombia. Fourteen (30%) applications received an initial positive decision, 25 (51%) conditional, and 9 (19%) negative. PAHO ERC identified ethical issues pertaining to informed consent/recruitment information in 31 (66%) of proposals, protection and care in 19 (40%), scientific design in 16 (34%), and confidentiality in 6 (13%). The mean number of amendments requested by PAHO ERC was 0.2 for proposal granted positive initial decisions, 3.6 for conditional, and 8.1 for negative. Forty (98%) of all finalized evaluations receive a final positive decision. Proposals subject to US or Canadian ethical rules or regulations were associated with higher approval rate on initial review and with a lower number of amendments. The author found no association between initial approval decision and proposal budget, number of investigators, type of PAHO research grant program, or level of scientific output in the country in which the study is held. Neither was an association found between these factors and the number of protocol amendments required by the committee. **Conclusions:** The ethics of research involving human participants remains an issue in Latin America, particularly the emphasis given to international ethical standards by investigators in their proposals and by ethical committees in their reviews. The knowledge, application and acceptance of existing standards within the region require further study.

DISTRIBUTION STATEMENT A
Approved for Public Release
Distribution Unlimited

T. FORREST KAYS, TSgt, USAF
NCOIC, IHS Education Programs

USUHS/PMB
4301 Jones Bridge Road
Bethesda, MD 20814-4799
COMM: (301) 295-9224/DSN: 312-295-9224
FAX: 295-9298
E-mail tkays@usuhs.mil
Website:
<https://www.afms.mil/afihs/>



Fax

To: AFIT From: Maj Fonseca
Fax: DSN: 285-2135 Pages: 16
Phone: _____ Date: September 23, 2003
Re: _____
☒ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

• Comments:

Public Release Clearance

UNCLASSIFIED INFORMATION ONLY